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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/039,927	03/16/1998	HENRY A. LESTER	A-63098-1/RF	1215

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EXAMINER	
PAK, MICHAEL D	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 02/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/039,927	Lester et al.
Examiner	**Art Unit**
Michael Pak	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 26, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *18-24* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *18-24* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 26 November 2001 (Paper No. 21) for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No.09/039,927 is acceptable and a CPA has been established. An action on the CPA follows.

2. The amendment filed 24 May 2001 (Paper No. 20) has been entered.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Applicant's arguments filed 24 May 2001 (Paper No. 20), have been fully considered but they are not found persuasive.

Specification

5. The disclosure is objected to because of the following informalities. Appropriate correction is required.

Page 4, Brief Description of the Drawings, figure legends do not agree with the figures 1-4 labels. For example figure 1a is referred to in the legend on page 4 as Figure 1 and then a-c which is not correct because the figure is labeled figure 1a. Furthermore, figure 2a is referred to in the legend on page 4 as Figure 2 and then a-d which is not correct because the figure is

labeled figure 2a and within figure 2a there are panels a-d. The relationship between the figure legend in the Brief Description of the Drawings on pages 4-5 should be carefully checked to see that it agrees with the labeling of the figures 1-4.

Applicants argue that amendment will be made of the Brief description when the formal drawings are submitted. Until such time the objection will be maintained.

Double Patenting

6. Claims 18-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 5,734,021 in view of Duprat et al.((22); BBRC, 1995) and Yatani et al.((12); Science, 1987) evidenced by Krapivinsky et al.(Nature, 1995).

Claims 1-5 of U.S. Patent No.5,734,021 disclose the inward rectifier potassium channels, KGA, encoded by low stringency hybridization with SEQ ID NO:1.

Yatani et al. teaches the inhibition of Ach(Ik) potassium channel with PTX and NAD.

Duprat et al. disclose the expression of GIRK1 and GIRK2 alone and in combination by injecting cRNAs into Xenopus oocyte (pages 659-661, figure 1-4). Duprat disclose that expression of GIRK3 and GIRK2 combination does not express any currents (page 660, middle of the upper paragraph), while GIRK2 alone or in combination with GIRK1 expresses an enhanced expression of

channels(page 659, figure 1). Duprat disclose that expression of GIRK3 and GIRK1 combination does not express any currents (page 660, middle of the upper paragraph), while GIRK1 alone or in combination with GIRK2 expresses an enhanced expression of channels(page 659, figure 1). Duprat et al. also disclose the decrease of inward rectifier current with Mg++ and ATP (pages 660-661, figures 2 and 4). Duprat et al. disclose the GIRK1, GIRK2, and GIRK3 nucleic acid cloned in the vector (page 658, methods and material section).

It would have been obvious to one of ordinary skill in the art to modify the claims of `021 to incorporate the method of Duprat et al. to isolated the nucleic acid form the given protein and nucleic acid sequence and assay to inhibit the channel currents because of the need to characterize the channels as inward rectifiers of specific characteristics. One of ordinary skill in the art would be further motivated to use the teaching of Duprat et al. and Yatani et al. because they are analogous references. Furthermore, Yatani et al. inward rectifier is a heteromultimer as taught by Krapivinsky et al.(Nature, 1995).

Applicants argue that neither `021 patent nor Yatani disclose heteromultimeric Kir3.0 channels. However, the obviousness double patenting includes Duprat et al. which does teach the heteromultimeric Kir3.0 and the motivation to use `021 claimed channel in the methods of Duprat et al.

Applicants argue that Kofuji et al. contribution date

antedates the Duprat et al. received date. However, a declaration is required to antedate a reference.

Claim Rejections - 35 USC § 112

7. Claims 18-24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what the metes and bounds of the terms, "Kir3.0", "Kir3.1/KGA", "Kir3.2", and "Kir3.3" are as recited in claims 1-17. The working examples of making Kir3.1/KGA disclose specific sequences SEQ ID Nos: 1 and 2. One of the factors which distinguishes the "Kir3.1/KGA" from other g-protein activated inward rectifier potassium channel subunits is the amino acid and nucleotide sequences of SEQ ID NO:1 and 2 discovered by the applicant. However, it is not clear whether the "Kir3.1/KGA" of the present invention are related to the specific disclosed channels or whether the applicants envision a "Kir3.1/KGA" which has no known relationship to the specific channels disclosed in the specification. The disclosure in the specification refers to a specific sequence in a cited reference for "Kir3.2" and "Kir3.3" (page 6, lines 1-9). One of the factors which distinguishes the "Kir3.2" and "Kir3.3" from other g-protein activated inward rectifier potassium channel subunits is the

specific sequence disclosed on page 6, lines 1-9. However, it is not clear whether the "Kir3.2" and "Kir3.3" of the present invention are related to the specific disclosed channels or whether the applicants envision a "Kir3.2" and "Kir3.3" which has no known relationship to the specific channels disclosed in the specification. The disclosure in the specification refers to "Kir3.0" as Kir3.1, Kir3.2, or Kir3.3, etc. (page 5, lines 23-24; page 6, lines 26-28). One of the factors which distinguishes "Kir3.0" from other g-protein activated inward rectifier potassium channels is the specific reference to "Kir3.0" as Kir3.1, Kir3.2, or Kir3.3, etc. (page 5, lines 23-24; page 6, lines 26-28). However, it is not clear whether the "Kir3.0" of the present invention are related to the specific disclosed channels or whether the applicants envision a "Kir3.0" which has no known relationship to the specific channels disclosed in the specification.

Claim 19 reference to 50% amino acid sequence identity is confusing as well since it is not clear whether Kir3.1, Kir3.2, or Kir3.3, etc. are specific species with specific amino acid sequence structure with which the percent amino acid sequence can be determined. Claims 18 and 20-24 encompass a method of claim 19 because the claims are generic to claim 19.

8. Claims 18-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims encompass a method of using variant Kir3.0 channel proteins which is naturally occurring but not disclosed in the specification nor to one of skilled in the art. Claimed method uses protein variants which encompass a large genus of Kir3.0 which are alleles or variants whose function has yet to be identified including from different species of animal because the structure of the newly identified naturally occurring channel is not known. The essential feature of the claimed invention is method whose novelty is in the Kir3.0 heteromultimeric inward rectifying potassium channels. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification. Thus, the genus of Kir3.0 channels structure cannot be envisioned.

Priority

9. Claim 18 is non-obviously broader than claims in the parent

application 08/066,371 and thus are not entitled to benefit of the earlier filing date.

The reason for the rejection has been set forth previously. The reason for the rejection is reiterated below.

Claims 18 are directed to proteins of Kir 3.2 and Kir 3.3 polypeptides. However, the specification references Lesage et al.(23) as the source for making Kir 3.2 and Kir 3.3 nucleic acid molecules and polypeptides (specification, page 29, lines 5-6). Lesage et al. disclosed Kir 3.2 and Kir3.3 in 1994 which is after the effective filing date of March 21, 1993. To receive priority to parent application (08/066,371, now US patent 5,744,324) filing date of March 21, 1993, the invention Kir 3.2 and Kir 3.3 of the present application must have been enabled in the parent application. Thus, at the time of the filing date of the parent application, the Kir 3.2 and Kir3.3 had not been disclosed and could not have been used at the time of the parent application. Accordingly, the nucleic acid encoding two or more Kir3.0 polypeptide subunits as well as the heteromultimer Kir3.0 channel composed of any two different combinations of Kir3.0 polypeptide subunit is not supported by the parent application. Although the parent application (08/066,371) does support the homomultimer channel composed of Kir3.1/KGA polypeptide of the disclosed sequence, claim 18 is directed to both homomultimers and heteromultimers, and thus are non-obviously broader than claims in the parent application 08/066,371 and thus are not entitled to

benefit of the earlier filing date.

Applicants argue that unless the filing date of the earlier application is needed to overcome a reference, there is no need for such a determination to be made. However, the 35 USC 102 and 103 rejections set forth below and previously are related to the priority date of the application. It is up to the applicant to decide whether the priority is needed to overcome the rejection.

Applicants argue that the office action also suggests that the claims of a patent having the identical disclosure of the present parent application render present claim 18 obvious and thus appears to be contradictory to the applicant. However, the the double patenting rejection is over the US patent 5,734,021 and the priority issue is to parent application 08/066,371 (now US patent 5,744,324).

The current application concept of heteromultimer was not disclosed in the specification of parent application 08/066,371. The issue is quite pertinent to the current rejections.

Claim Rejections - 35 USC § 102

10. Claims 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Yatani et al.((12); Science, 1987) with evidence by Krapivinsky et al.(Nature, 1995).

The reason for the rejection has been set forth previously and reiterated below.

Yatani et al. teaches the method of reducing the current of

Kir 3.0 channel with NAD and PTX (page 209, middle column, first paragraph). Although Yatani et al. does not call the potassium channel conducting the I(KAch) current Kir 3.0, it is the same channel with same inherent properties. The claims are drawn to Kir3.0 channel generically and Krapivinsky teach that the inward rectifier potassium channels are heteromultimers.

Applicants argue that Yatani does not disclose forming a functional Kir3.0 channel from at least two different Kir3.0 polypeptides. However, the claims are drawn generically to a method using Kir3.0 polypeptides and the Yatani et al. potassium channels are formed inherently heteromultimers as taught by Krapivinsky et al.

11. Claims 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Karschin et al.((8); PNAS, 1991) with evidence by Krapivinsky et al.(Nature, 1995).

The reason for the rejection has been set forth previously and reiterated below.

Karschin et al. disclose the 5-HT/5-HT receptor and Ach/Ach receptor activations of I(KAch) inwardly rectifying potassium channel current (page 5696, figure 2 and 3). Potassium concentration was varied to show decrease in the reversal potential of the Ach induced I(KAch) current (page 5695, second column, middle of the paragraph).

Although Karschin does not call the potassium channel conducting the I(KAch) current Kir 3.0, it is the same channel with same inherent properties. The claims are drawn to Kir3.0 channel generically and Krapivinsky teach that the inward rectifier potassium channels are heteromultimers.

Applicants argue that Karschin does not disclose forming a functional Kir3.0 channel from at least two different Kir3.0 polypeptides. However, the claims are drawn generically to a method using Kir3.0 polypeptides and the Karschin et al. potassium channels are formed inherently heteromultimers as taught by Krapivinsky et al.

12. Claims 18-24 are rejected under 35 U.S.C. 102(a) as being anticipated by Duprat et al.((22); BBRC, 1995).

The reason for the rejection has been set forth in the previous office actions.

Applicants argue that Kofuji et al. contribution date antedates the Duprat et al. received date. However, a declaration is required to antedate a reference.

Applicants argue that Mg nor ATP were described as inhibitors. However, since the Mg and ATP blocks or inhibits the potassium current, it is an inhibitor compared to the control without Mg.

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Michael D. Pak

Michael Pak
Primary Patent Examiner
Art Unit 1646
7 February 2002